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FOR: OPHTHALMIC APPARATUS

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APPLICABLE ITEMS CHECKED:

XX PATENT APPLICATION (pages 1-13 of specification, 7 claim(s) (page(s) 11-12), abstract and declaration and power of attorney)

       DESIGN APPLICATION (specification, claim, declaration and power of attorney and photograph(s))

XX FORMAL DRAWINGS (4 sheets) (NI A4)

       INFORMAL DRAWINGS (       sheets)

       RECORDATION FORM COVER SHEET and ASSIGNMENT  
(to be recorded and returned to the undersigned)

XX PRIORITY CLAIM - applicant(s) claim the benefit of priority of the following application(s):

Japanese Patent Appln. No. 71615/98  
filed March 20, 1998.

XX PRIORITY DOCUMENT(s)

XX Enclosed        Not Enclosed

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XX EXPRESS MAIL CERTIFICATION

       OTHER -

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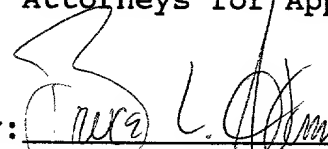
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<u>  0  </u> Total Claims in Excess of 20	\$	\$
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TOTAL	\$ 760.00	\$

Respectfully submitted,

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OPHTHALMIC APPARATUS

5

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention relates to an ophthalmic apparatus, and more particularly to an ophthalmic apparatus for non-contact measurement of the physical  
10 quantity of lacrimal fluid collected on the lower eyelid.

Description of the Prior Art

Recent years have seen an increase in the numbers of people suffering from dry eyes caused by  
15 working with VDTs (visual display terminals) or working in rooms in which the air is dried out by air conditioning systems. Dry eyes can result in a number of ophthalmic conditions, such as damage to the corneal epithelium and conjunctiva. As such, the diagnosis of dry  
20 eye syndrome is becoming an important part of ophthalmic diagnostic procedure.

Conventional methods of diagnosing dry eye include examining vital stainings and volume of lacrimal fluid. However, such methods involve discomfort to the  
25 patient caused by the application of a solution or contacting the eye with an instrument. To detect the dry



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eyes in a non-contact manner, methods have been tried involving projecting a beam of coherent light onto the eye and examining interference fringes formed by the tear film layer. In the apparatus of such systems, color  
5 images of interference fringes (rainbow-colored interference patterns) formed by the tear film lipid layer of an eye to be examined are photoelectrically converted by a photoelectric element in a light-receiving system and shown on a display means. The presence of dry  
10 eye can then be readily diagnosed by examining the interference pattern indicating the condition of the tear film layer.

However, a problem with the interference fringes produced by tear film lipid layer with the  
15 conventional systems is the low contrast of the fringes, which makes it difficult to obtain a good ophthalmic diagnosis based on the fringes. Another problem is that the examiner directly observes the color patterns on the display screen to evaluate the grade of the dry eye  
20 condition, so only qualitative measurement is possible.

The object of the present invention is to provide an ophthalmic apparatus that enables diagnosis of dry eye condition by quantitatively measuring the physical quantity of lacrimal fluid collected on the  
25 border of the lower eyelid.

# SUMMARY OF THE INVENTION

In accordance with the present invention, the above object is attained by an ophthalmic apparatus comprising a light control means formed with an aperture  
5 having a predetermined shape, means for projecting the aperture onto a surface of tear film collected on a lower eyelid, means for imaging the aperture projected on the tear film surface, and a means for evaluating a physical quantity of lacrimal fluid based on the image of the  
10 aperture thus obtained.

The tear film surface on the border of the lower eyelid (tear meniscus) functions like a concave mirror, so the magnification factor of the imaged aperture depends on the radius of meniscus curvature. In  
15 this invention, the magnification factor of the aperture image is obtained, giving the radius of meniscus curvature. The radius of meniscus curvature has a bearing on the volume of lacrimal fluid affecting the dry eye condition, so obtaining the radius of meniscus curvature  
20 makes it possible to evaluate quantitatively the degree of severity of the dry eye condition, or the phase into improvement thereof.

The above and other features of the present invention will become apparent from the following  
25 description made with reference to the drawings.

## BRIEF EXPLANATION OF THE DRAWINGS

Figures 1a and 1b are diagrams illustrating the state of tear film collected in the lower eyelid, and Figures 1c and 1d are diagrams illustrating the  
5 relationship between the radius of meniscus curvature and the volume of lacrimal fluid;

Figure 2a is an optical diagram of the principle of the measurement of the radius of meniscus curvature, Figure 2b is a diagram illustrating the  
10 formation of a grid image by the tear meniscus, and Figure 2c is a diagram of the grid image displayed on a monitor;

Figure 3 is a diagram of the arrangement of the apparatus of the invention;

15 Figure 4 is a diagram of an example of grid dimensions;

Figure 5 is a diagram of another example of grid dimensions; and

Figure 6 is a diagram of the grid image  
20 projected onto the center and peripheral portions of the tear meniscus.

## DESCRIPTION OF THE PREFERRED EMBODIMENT

Figure 1 illustrates the principle of a  
25 meniscometer for measuring the quantity of lacrimal fluid. A tear film from the outermost layer of the eye is

comprised of lipid, aqueous and mucin layers; the lipid layer is secreted from the Meibomian gland and is subjected to pressure when the eyelid closes. When this happens, a tear film 3 accumulates on the lower eyelid border, as shown in Figures 1a and 1b. An examination for dry eye is conducted with respect to the volume of lacrimal fluid on the border of the lower eyelid, with less lacrimal fluid indicating a more severe dry eye condition.

10           The relationship between tear volume  $V$  and radius of meniscus curvature  $r$  of the surface of the tear film 3 is that, since the cornea 4 and the eyelid 2 are both curved, a larger  $V$  results in a larger  $r$ . This relationship is illustrated by Figures 1c and 1d. If  
15   lacrimal fluid volume  $V$  increases from  $V_1$  to  $V_2$ , the radius of meniscus curvature also increases from  $r_1$  to  $r_2$ . Here,  $\theta_1$ ,  $\theta_2$  are constants determined by the surface tension. While these constants vary according to the severity of the dry eye condition, compared to the change  
20   in  $r$ , such change is negligibly small.

          In the present invention, the volume  $V$  of lacrimal fluid is determined by measuring the radius of meniscus curvature  $r$  (tear meniscus). For this, in accordance with the invention, a grid image is projected  
25   onto the tear film surface, and the physical quantity of the lacrimal fluid, that is, the radius of meniscus

curvature  $r$ , is measured by analyzing the grid image.

Figure 2 shows the configuration of this principle.

In Figure 2a, light from a lamp 10 passes through an objective lens 11 and illuminates a grid 12, used as a light control means, which is projected onto a concave mirror 13 serving as a tear meniscus model. A grid image 14 is formed by the concave mirror 13, and, via a projection lens 15, this grid image 14 is imaged by an imaging means such as a camera 16.

With respect to Figure 2b, the grid having a height  $d$  at a working distance  $W$  from the concave mirror (tear meniscus) of curvature radius  $r$  is transformed into an image  $d_1$  at a distance  $W_1$  from the concave mirror. Here,  $W_1 = (rW)/(2W - r)$  is obtained from the well-known relationship  $2/r = (1/W) + (1/W_1)$ , and  $d_1 = (d/W) \times W_1$  is obtained from the relationship  $d_1/d = W_1/W$ .

From the above two equations,

$$d_1 = (d/W) \times \{rW/(2W - r)\},$$

$$d_1 = \{dr/(2W - r)\}.$$

Here, if  $W \gg r$  (for example,  $W = 24$ ,  $r = 0.3$ ), then  $2W - r \doteq 2W$ , providing the approximation formula  $d_1 \doteq (dr/2W)$ , thus  $r = (d_1/d) \times 2W$ .

If grid image  $d_1$  is magnified by a magnification of  $\beta$  to the size  $D$  shown in Figure 2c, since  $D = \beta \times d_1$ , then  $r = (D/\beta) (2W/d)$ . Thus, if the monitor is a 14-inch television monitor, for example, then  $\beta = 190.9$ , and as a



result,  $r = (D/190.9) (2W/d)$ .

In grid size (grid pitch),  $d$  is a constant, and  $W$  is the working distance value determined by the design. While this might be changed somewhat in the alignment, it is a small enough value to be disregarded. Thus, the curvature radius  $r$  of the tear meniscus for lacrimal fluid volume  $V$  can be found by measuring the size of the grid image  $D$  displayed on the monitor.

Figure 3 illustrates a specific apparatus based on the principle described above. With reference to Figure 3, light from a halogen lamp 21 passes through a filter 22, which blocks heat rays, a polarizing plate 23 and an illumination lens 24, and is reflected by a mirror 25 such as a half-mirror or aperture mirror. The light reflected by the mirror 25 passes through an objective lens 26 and illuminates a grid 27 having a plurality of apertures, that functions as a light control means. The grid 27 thus illuminated is projected onto a meniscus 28 of tear film collected on a lower eyelid 36.

As shown in Figure 4, the grid 27 comprises a plurality of apertures in the form of slits (five in this example) each measuring  $D_3$  by  $D_5$  arranged on a  $D_1$  by  $D_2$  substrate, with the slits being equidistantly spaced apart by a distance  $D_4$ , and provided with a white space  $D_6$  above and below and a white space  $D_7$  on each side. The dimensions are set at, for example, the following:  $D_1 =$

48.0 mm,  $D_2 = 15.0$  mm,  $D_3 = 9.0$  mm,  $D_4 = 4.0$  mm,  $D_5 = 4.0$  mm,  $D_6 = 6.0$  mm, and  $D_7 = 3.0$  mm. In this example, the  $d$  of Figure 2b (grid pitch) is  $d = D_4 + D_5 = 8$  mm.

The light from the projected grid 27 is  
5 reflected by the tear meniscus 28, forming a grid image  
in the vicinity of the tear meniscus. The grid image thus  
formed by the tear meniscus passes through objective lens  
26, mirror 25, projection lens 29 and polarizing plate 30  
and is picked up by a CCD camera 31, and the image is  
10 subjected to image processing by a processor 32. This  
processor 32 can, for example, be used to obtain the  
pitch of the grid image on the camera corresponding to  $d$   
 $= D_4 + D_5$  by binarizing the image signal and obtaining the  
pixel coordinates for each aperture. The processor 32  
15 also calculates the pitch  $d_1$  of the grid image formed by  
the tear meniscus, taking into account the lens  
magnification factor, and evaluates the radius of  
curvature  $r$  of the tear meniscus 28 in accordance with  
the above equation  $r = (d_1/d) \times 2W$ .

20 As described above, in the formation of the  
grid image, the tear meniscus 28 has the function of a  
concave mirror, and, therefore, the factor by which the  
grid image formed is magnified depends on the radius of  
meniscus curvature  $r$  of the tear meniscus. Obtaining the  
25 radius of meniscus curvature makes it possible to  
evaluate quantitatively the severity of the dry eye

condition. The outcome of each calculation and the evaluation can be displayed on a monitor 33.

The polarizing plate 23 arranged in the illumination and projection system and the polarizing plate 30 arranged in the imaging system both have the same orientation so as to transmit light in the same direction. As the tear meniscus is liquid, the polarized state is not readily broken down in the course of reflection, so using the polarizing plates makes it possible to improve the signal-to-noise (S/N) ratio during imaging.

Figure 5 shows another example of a grid. In this example, the grid has a finer pitch. The dimensions are  $D_1 = 48.0$  mm,  $D_2 = 15.0$  mm,  $D_3 = 9.0$  mm,  $D_4 = 2.0$  mm,  $D_5 = 2.0$  mm,  $D_6 = 7.0$  mm, and  $D_7 = 3.0$  mm, and the grid pitch will be 4 mm.

As to what the degree of precision of  $r$  is when the working distance  $W$  is 24 mm, the grid pitch is the 8 mm of Figure 4, and the monitor 33 is a 14-inch model, the following is the result of an actual measurement carried out with the apparatus of Figure 3 (not using the processor 32), using a glass tube of radius 0.30 mm and piano wire of radius 0.15 mm. In the case of a 14-inch monitor,  $\beta = 190.9$ , so from the above equation, curvature radius  $r$  will be as follows.

$$r = (D/190.9) \times \{(2 \times 24)/8\} = 0.0314 \times D.$$

In the case of the glass tube of 0.30 mm radius, the grid pitch D on the monitor was 9.55 mm, this being the mean value of ten measurements obtained using a ruler, so  $r = 0.0314 \times 9.55 = 0.30$  mm, an accurate value. In the case of the piano wire of radius 0.15 mm, the average of ten measurements of D was 4.58 mm, so  $r = 0.0314 \times 4.58 = 0.14$  mm. The degree of error is a mere 0.01 mm, confirming that the curvature radius of the meniscus can be measured with quite a degree of precision.

The tear meniscus 28 is a horizontally elongated shape, with the angle changing going toward the outside corner of the eye. So, by making the grid 27 rotatable, as shown in Figure 6, the orientation of the grid 27 can be changed between the middle grid image 40 projected on the tear film surface and the peripheral grid image 41. For example, the grid could be adjusted so that straight lines at right-angles to the grid apertures come to a point, making it possible to efficiently direct the illuminating light onto the tear meniscus.

As described in the foregoing, in accordance with the present invention, physical quantities such as the radius of meniscus curvature of tear film can be calculated based on a grid aperture image projected onto the tear film surface, thereby making it possible to quantitatively evaluate the degree of severity or change of a dry eye condition.

What is claimed is:

1. An ophthalmic apparatus comprising:  
a light control means formed with an aperture  
having a predetermined shape;  
5 means for projecting the aperture onto a  
surface of tear film collected on a lower eyelid;  
means for imaging the aperture projected on the  
tear film surface; and  
a means for evaluating a physical quantity of  
10 lacrimal fluid based on the image of the aperture thus  
obtained.
2. An ophthalmic apparatus according to claim 1,  
wherein a radius of meniscus curvature is calculated  
based on the aperture image.
- 15 3. An ophthalmic apparatus according to claim 2,  
wherein a dry eye condition is evaluated based on the  
calculated radius of meniscus curvature.
4. An ophthalmic apparatus according to claim 1,  
wherein the light control means is a grid comprised of a  
20 plurality of slit-shaped apertures arranged in an  
equidistant arrangement.
5. An ophthalmic apparatus according to claim 1,  
wherein the projection means and imaging means are each  
provided with a polarizing plate.
- 25 6. An ophthalmic apparatus according to claim 1,  
wherein an orientation of an aperture can be adjusted in

accordance with a position of the aperture projected on the tear film surface.

7. An ophthalmic apparatus according to claim 1,  
wherein an optical system of the projection means and an  
5 optical system of the imaging means are arranged  
coaxially.

ABSTRACT OF THE DISCLOSURE

A grid formed with apertures of a predetermined shape is illuminated with light from a lamp and projected  
5 onto a tear meniscus accumulated on the lower eyelid. The aperture image projected on the tear film is imaged by a CCD camera. The tear meniscus functions as a concave mirror, so that the magnification factor depends on the radius of meniscus curvature. A processor calculates the  
10 magnitude of the grid image and evaluates the radius of meniscus curvature. Since the volume of lacrimal fluid varies depending upon the radius of meniscus curvature, the latter is used as a value representing the lacrimal fluid volume for dry eye diagnose purposes.

FIG. 1a

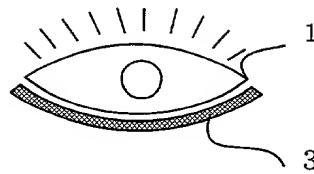


FIG. 1b

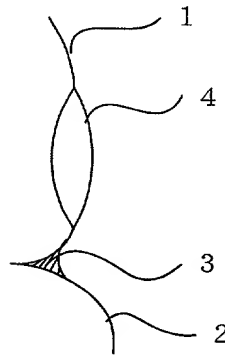


FIG. 1c

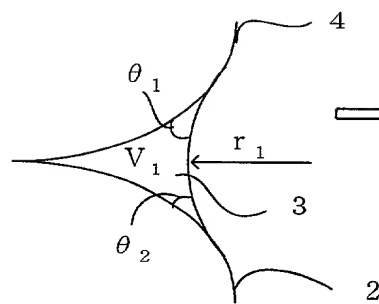
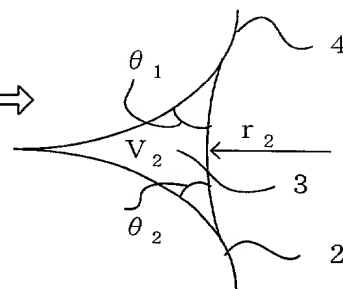


FIG. 1d





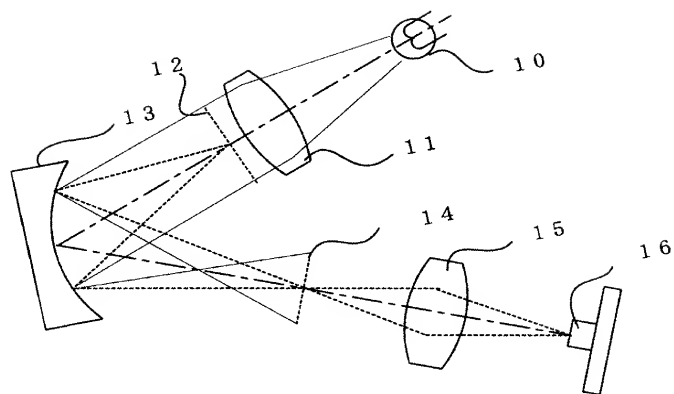


FIG. 2a

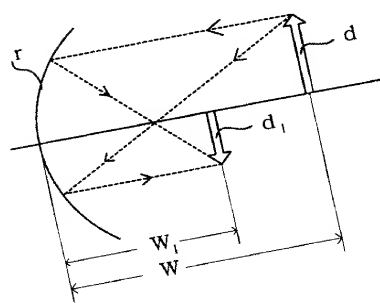


FIG. 2b

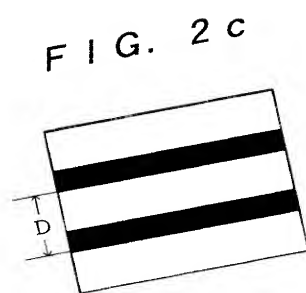
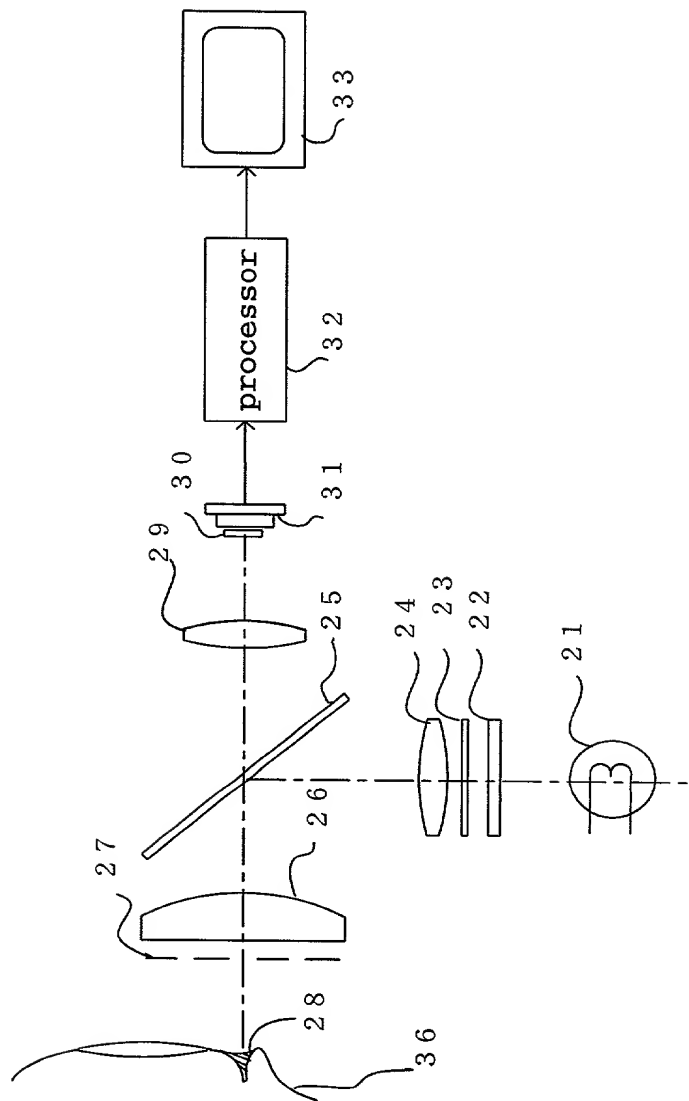


FIG. 2c

**FIG. 3**



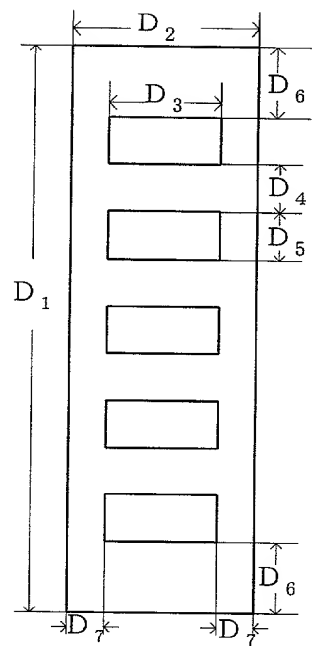


FIG. 4

FIG. 6

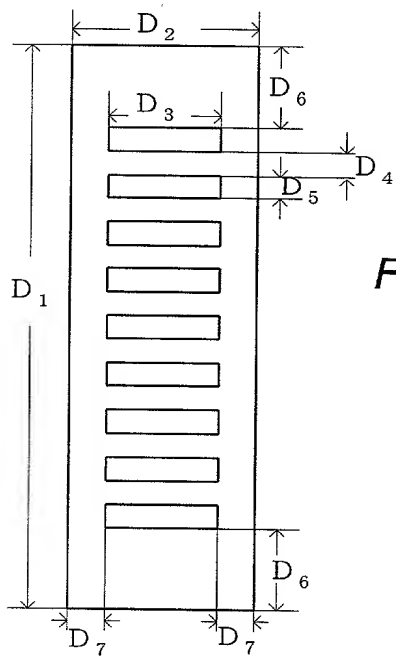
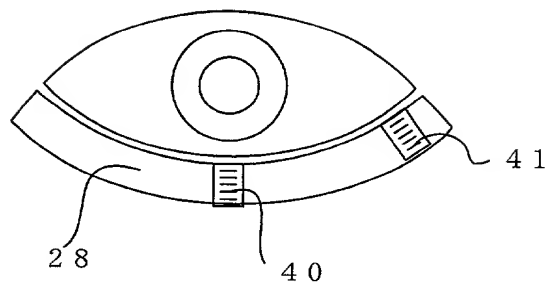


FIG. 5

# DECLARATION FOR PATENT APPLICATION

As a below named inventor, I hereby declare that my residence, post office address and citizenship are as stated below next to my name; I believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

## OPHTHALMIC APPARATUS

the specification of which (check one); ☒ is attached hereto; ☐ was filed on \_\_\_\_\_ as Application Serial No. \_\_\_\_\_ and was amended on (or amended through) \_\_\_\_\_ (if applicable). I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment(s) referred to above. I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a). I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate having a filing date before that of the application on which priority is claimed.

### Prior Foreign Application(s)

71615/98	Japan	20/03/98	Priority Claimed	
(Number)	(Country)	(Day/Month/Year Filed)	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
(Number)	(Country)	(Day/Month/Year Filed)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
(Number)	(Country)	(Day/Month/Year Filed)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
(Number)	(Country)	(Day/Month/Year Filed)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
(Number)	(Country)	(Day/Month/Year Filed)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
(Number)	(Country)	(Day/Month/Year Filed)	<input type="checkbox"/> Yes	<input type="checkbox"/> No

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

(Application Serial No.)	(Filing Date)	(Status - Patented, Pending or Abandoned)
(Application Serial No.)	(Filing Date)	(Status - Patented, Pending or Abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

### POWER OF ATTORNEY

I (we) hereby appoint Bruce L. Adams, Registration No. 25,386, Van C. Wilks, Registration No. 25,027 and Franco S. De Liguori, Registration No. 36,497 whose post office address is: Adams & Wilks, 50 Broadway, 31st Floor, New York, New York 10004, as my (our) attorneys with full power of substitution and revocation, to prosecute this application, and to transact all business in the United States Patent and Trademark Office connected therewith.

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Date ✓	Signature ✓

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Date ✓	Signature ✓

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State or Country	State or Country
Date ✓	Signature ✓